DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
MJ485M

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

March 12, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Stuart L. Foster
President
Baxter Healthcare Corporation
Cardiovascular Group
17221 Red Hill Avenue
Irvine, CA 92614

WL-26-9

Dear Mr. Foster:

During an inspection of your firm located at 17221 Red Hill Avenue, Irvine, CA 92614 conducted from January 27 to February 5, 1999, our investigator determined that your firm manufactures pulmonary artery catheters. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities and controls used for its manufacturing, packing, storage, or installation, are not in conformance with the Good Manufacturing Practice (GMP) requirements set forth in the Quality System Regulation as prescribed by Title 21, Code of Federal Regulations, (CFR) Part 820, as follows:

1. Failure to validate computer software used as part of production for its intended use according to an established protocol [21 CFR 820.70(i)]. Specificially, your firm does not have sufficient documented evidence, which provides a high degree of assurance that the computer software used as part of production for the pulmonary artery extrusion process meets its pre-determined specifications and quality attributes.

2. Failure to validate production processes with a high degree of assurance where the results of a process cannot be fully verified by subsequent inspection and test [21 CFR 820.75]. Specificially, your firm does not have sufficient documented evidence, that the Pulmonary Artery Catheter balloon forming,and the polyethylene(PVC) compounding processes meet their pre-determined specifications and quality attributes.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violation identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge that you have submitted to this office a response concerning our investigator's observations noted on the form FDA-483. We also acknowledge meeting with members of your company on 3/5/99 to discuss the investigator's observations. Although your response indicates that corrective measures have been undertaken they have not been completed. For this reason the adequacy of your response can not be fully evaluated. We request that these materials be provided to our office when the tasks have been completed. Your response does not provide documented evidence which provide a high degree of assurances that your balloon forming, PVC compounding and the computerized extrusion processes have been validated. A reinspection will be necessary to assure that your corrections are adequate.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no request for Certificates to Foreign Governments for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunctions, and/or civil penalties.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612-2445

Sincerely,

Elaine C. Messa
District Director

cc: John Quick, CorporateVice-president for Quality
Baxter Healthcare Corporation
1 Baxter Parkway
Deerfield IL 60015

State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Administration
601 North 7th Street, MS-357
P.O. Box 942732
Sacramento, CA 94234-7320